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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,506	05/25/2001	Ghita Lanzendorfer	BEIERSDORF70	8673

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EXAMINER
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YU, GINA C

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 02/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/744,506	<b>Applicant(s)</b> LANZENDORFER et al.	
	<b>Examiner</b> Gina C. Yu	<b>Art Unit</b> 1617	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 November 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 8,9 and 19-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8,9 and 19-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
     If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |                                                                                              |                                                                             |
|----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

Receipt is acknowledged of Amendment filed on November 7, 2003. Claims 8, 9 and 18-23 are pending. Claim rejections made under 35 U.S.C. § 112, second paragraph as indicated in the previous Office action dated August 7, 2003, are withdrawn in view of applicants' amendment. Claim rejections made under 35 U.S.C. § 103 (a) in view of Caserio et al. (US 4664910) as indicated in the same Office action are withdrawn in view of the claim cancellation and amendments by applicants. Claim rejections made under 35 U.S.C. § 103 (a) in view of Caserio et al. and Tisdale et al. (US 6103246), and in view of Caserio et al. and Pittrof et al. (US 5376646) are both withdrawn and modified to address the new claim limitations.

#### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 8, 9, 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caserio et al. (US 4664910) ("Caserio" hereunder) in view of Tisdale et al. (US 613246) ("Tisdale").

Caserio teaches a topical composition for skin or hair which comprises 0.1-20 % of cholanic acid derivatives and a powder absorbent. Optionally, water and/or other liquid carriers can be incorporated in the composition. The reference teaches that lithocholic acid, deoxydycholic acid, and cholic acid are preferred cholanic acid derivatives. Emollients, propellants, organic solvents, humectants, and thickeners are taught as cosmetically acceptable carriers. The reference also teaches to add

antioxidants. Example 5 shows a composition comprising 5% taurocholic acid and cosmetic auxiliaries. See abstract; col. 1, line 66-col. 2, line 37; col. 3, lines 64-66; col. 4, lines 6-11; col. 6, line 59 – col. 7, line 11; col. 8, line 13-col. 8, line 50.

While the reference lacks specific teachings of the weight of the antioxidants to be used, examiner notes that, since the general condition of using antioxidants in the cosmetic composition is taught, discovering the optimum or workable ranges involves only routine skill in the art because of the expectation of achieving a composition with optimum antioxidant effects. The reference in fact discloses a composition in Example 6 comprising 1.03 % of pigment and antioxidant.

Regarding the phrase “a barrier strength effective amount” in instant claim 20, examiner respectfully points out that the instant invention requires the same amount of a bile acid or salt as the prior art uses, which is 0.01-0.5 %. For claims 19-20 which are directed to method of applying 0.01-0.5 % of a bile acid or its salt, examiner asserts that the claimed method is practiced by the topical application of the bile acid-containing prior art composition. Any properties exhibited by or benefits provided the compositions are inherent and are not given patentable weight over the prior art. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicants disclose and/or claims are necessarily present.

Caserio fails to teach encapsulated forms.

Tisdale teaches that liposomes (encapsulated preparation forms) penetrate into the deep underlying layers of the skin where they deliver their active agents in a time-

release action. See col. 2, lines 38 –59. The reference also teaches that liposomes encapsulate “a portion of the solution” in which the liposome is found. See instant claim 18.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the Caserio invention by formulating the liquid composition in Caserio in the form of liposomes as taught by Tisdale because of the expectation of successfully achieving a cosmetic composition with enhanced skin penetration and time-released action.

2. Claims 22-23 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Caserio and Tisdale as applied to claims 8, 9, 18-21 above, and further in view of Pittrof et al. (US 5376646).

Caserio and Tisdale fail to teach vitamin E.

Pittrof teach cosmetic compositions comprising a cholanic acid and a lipid. Examples show a micelle solution mixed with 2% tocopherol and sodium glycocholate. See col. 6, line 60 – col. 7, line 12.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the composition of the combined references by adding the tocopherol acetate as taught by Pittrof to the composition because the Caserio reference teaches that antioxidants are added to its composition, and Pittrof teaches tocopherol acetate as an antioxidant that can be combined with bile acid salt. Thus, the skilled artisan would have been motivated to look to Pittrof for antioxidants that are combinable with bile acid salts.

***Response to Arguments***

Applicant's arguments filed on November 7, 2003 have been fully considered but they are not persuasive.

Applicants argue that the weight range of cholanolic acid in Caserio does not render applicants' weight range allegedly because the bile acid of the present invention is in a different form. The argument is unpersuasive because both inventions are directed to topical, cosmetic compositions. Applicants' argument that a skilled artisan would be motivated to use different amount of same cosmetic ingredient to formulate encapsulated forms is unsupported and thusly unpersuasive.

Applicants' argument that Caserio does not recognize using antioxidants as being a results effective variable is also unpersuasive because, as the reference teaches, the purpose of using antioxidants in cosmetic art is obviously to achieve antioxidative effect.

While applicants argue that using the bile acid to strength skin barrier is a new use, examiner notes that the claimed method is the topical application of the bile-acid containing composition, which is old and well known in the art. The fact that all the claims of in In re Spada were composition claims are viewed irrelevant in this case because that does not change the fact that the Caserio bile acids perform the same functions as applicants are claiming in this case.

While applicants' argument that the rejection made in view of Caserio and Tisdale were inappreciable hindsight, applicants merely assert that the Caserio reference alone fails to teach adding additives or formulating into a different form of a composition.

Examiner respectfully points out that the rejections were made in view of the combined teachings of analogous art. Both Caserio and Tisdale were available to skilled artisans at the time of the present invention. While applicants assert that “the practitioner would want immediate removal of excessive moisture or grease due to an accumulation of sebum and/or sweat”, examiner views that the argument is unsupported. The reference in col. 5, lines 1-7 states that after the application of the composition “the skin will remain in a healthy pliable state, usually for several hours, and will not become excessively dry”. See also col. 5, lines 41- 50. In view of the teaching, is viewed that the prolonged action of the bile acid/salts is certainly desirable in the Caserio invention. Examiner thus maintains the position that enhanced penetration and timed release of the bile acid/salts is the motivating factor to combine the teachings of the Caserio and Tisdale.

Examiner respectfully disagrees with applicants’ remarks that “Pittrof was primarily relied upon their teachings of liposomes”. As reiterated in the rejection above, the reference was cited to show that it is old and well known to add vitamin E in cosmetic preparation.

### ***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1617

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 571-272-0635. The examiner can normally be reached on Monday through Friday, from 8:30 AM until 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Gina Yu  
Patent Examiner

  
**SREENI PADMANABHAN**  
**SUPERVISORY PATENT EXAMINER**

4/9/04